Art Unit 125

Paper No. 13

MAILED

Appeal No. 620-40

JUN 28 1985

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PAT. & T. M. OFFIC' COARD OF APPEAL

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte Josephus Brugmans,
William Pollack,
Paul A. J. Janssen
and
Daniel Tripodi

Application for Patent filed February 2, 1981, Serial No. 230,578; a Continuation of Serial No. 067,505 filed August 17, 1979; a Continuation of Serial No. 944,520 filed September 30, 1978, Abandoned; a Continuation of Serial No. 799,893 filed May 23, 1977, Abandoned; a Continuation of Serial No. 591,795 filed June 30, 1975, Abandoned; a Continuation-in-Part of Serial No. 424,030 filed December 12, 1973, Abandoned; a Continuation-in-Part of Serial No. 281,367 filed August 17, 1972, Abandoned. Aiding the Regression fo Neoplastic Disease with 2,3,4,6-Tetrahydro-6-Phenylimidazo (2,1-b) Thiazole.

Geoffrey G. Dellenbaugh et al. for appellants.

Primary Examiner - Jerome D. Goldberg.

Before Blech, Goldstein and Pellman, Examiners-in-Chief. Goldstein, Examiner-in-Chief.

This appeal was originally taken from the examiner's final rejection of claims 1 to 19. Subsequently, the examiner allowed claims 3 to 15, 18 and 19 and appellants cancelled claims 16 and 17. The claims remaining on appeal are thus claims 1 and 2.

Appeal No. 620-40 Claim 1 is illustrative and reproduced below. 1. A process of aiding regression and palliation of neoplastic disease which comprises the systemic administration to human and animal subjects hosting the neoplastic disease of an effective antineoplatic amount of a member selected from the group consisting of 2,3,5,6-tetrahydro-6-phenylimidazol2,1-bl thiazole and the therapeutically active acid addition salts thereof in a pharmaceutical carrier. The sole reference relied on by the examiner on appeal is: Smith et al. (Smith), "Preliminary Report of the Use of Levamisole in the Treatment of Bladder Cancer," Cancer <u>Treatment Reports</u>, <u>62</u>(11), Nov., 1978, pp. 1709-1714. Claims 1 and 2 have been finally rejected under 35 U.S.C. 101 for lack of demonstrated utility and under the first paragraph of 35 U.S.C. 112 "as being based on an insufficient disclosure. The rejection under 35 U.S.C. 112 is presumably one for lack of enablement. We shall not affirm these rejections. We have carefully considered the examiner's statement of the rejection, the Smith article relied on by the examiner to support his position and appellants' arguments in the reply brief. We find appellants' arguments to be convincing, particularly in view of the Smith article's authors' own characterization of the number of patients and length of follow-up involved as being "obviously too small to permit any statements with regard to the efficacy of levamisol as an immune adjuvant in the treatment of bladder cancer. Furthermore, as we have already indicated in our decision on appeal of appellant's parent application, there appears to be a theoretical basis for the expectation that immune response therapy would be less histological type dependent than cytotoxic therapy. - 2 -

Appeal No. 620-40 The decision of the examiner is reversed. REVERSED Samuel H. Blech Examiner-in-Chief Melvin Goldstein Examiner-in-Chief Irvin () R. Pellman Examiner-in-Chief ) Leonard P. Prusak, Esquire Johnson and Johnson 501 George Street New Brunswick, NY 08903